

## Add buffer

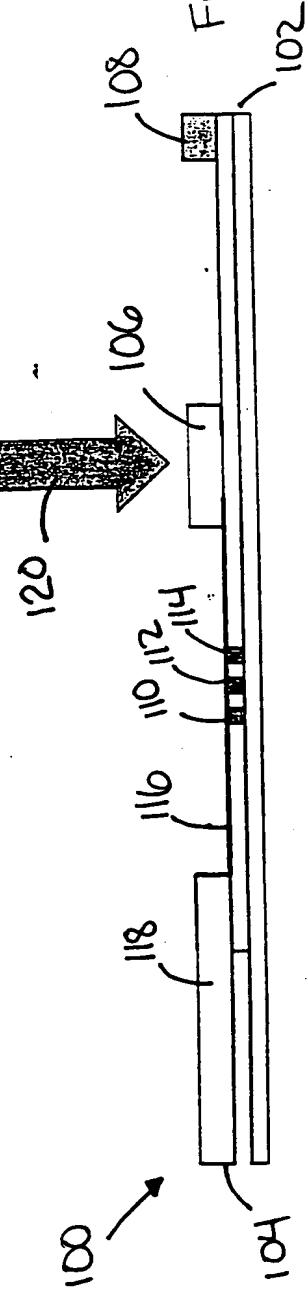


Fig. 2A

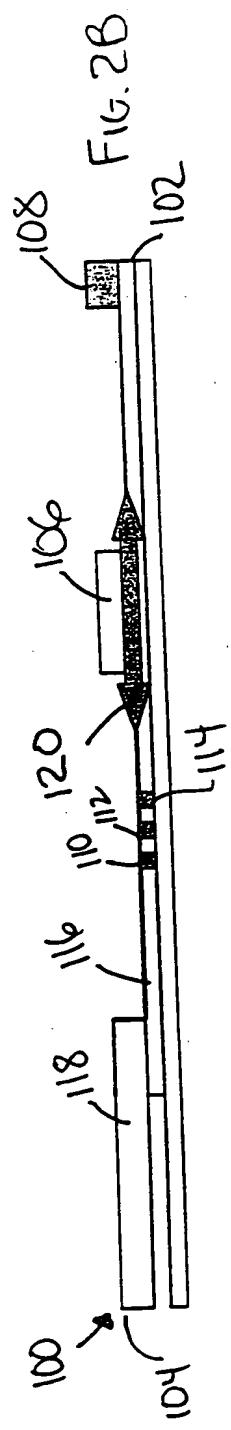
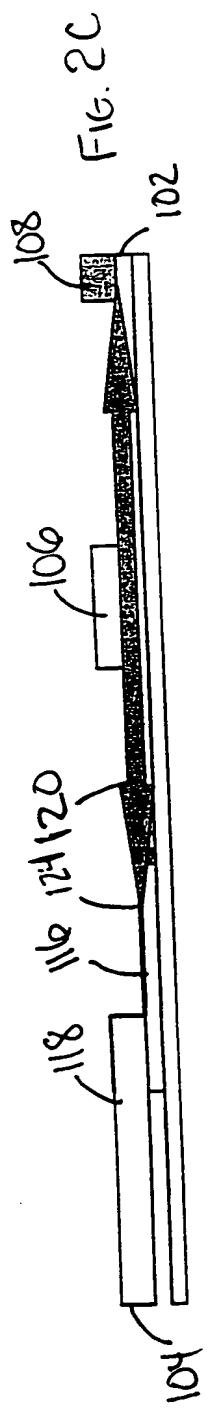


Fig. 2B



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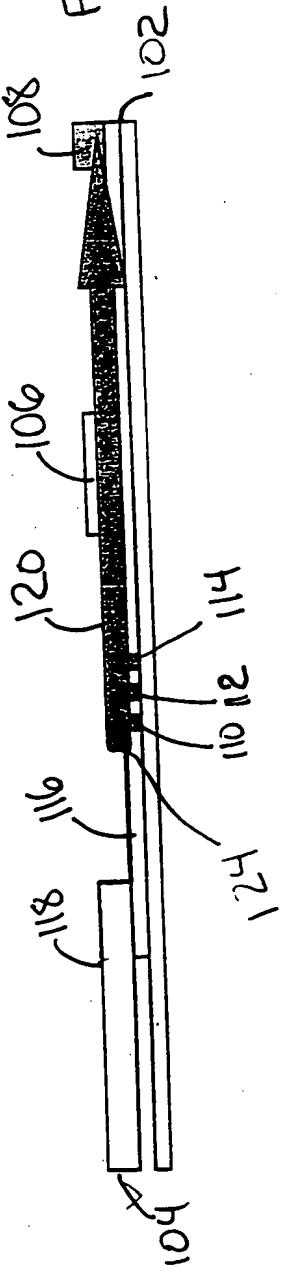


Fig. 20

122 → Add SAMPLE

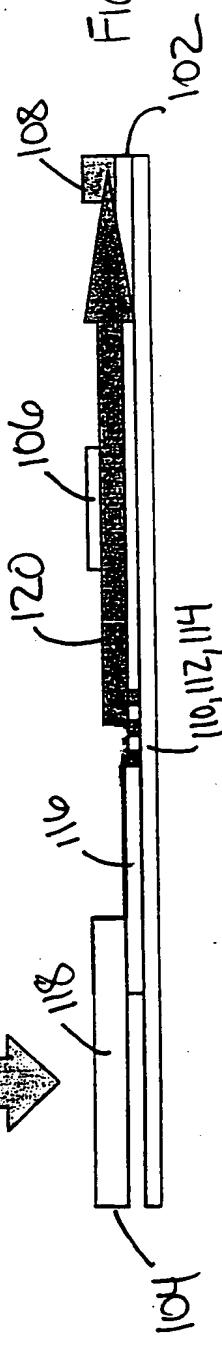


FIG. 2E

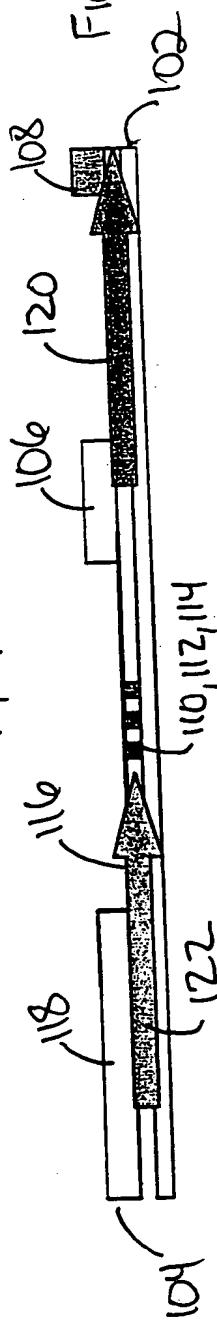


FIG. 2F

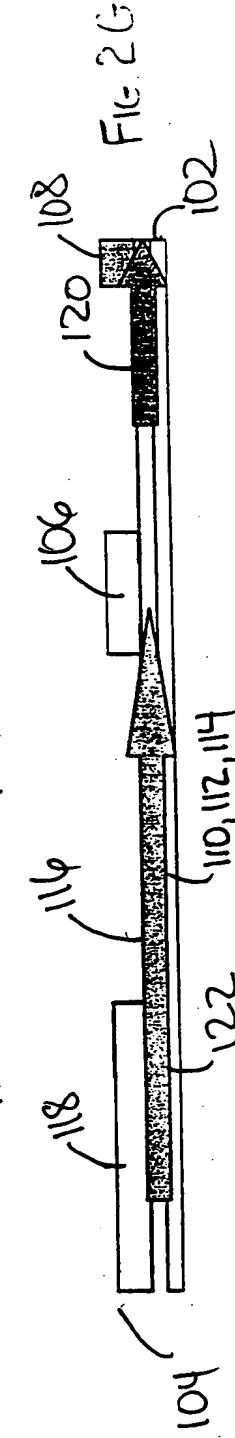


FIG. 2G

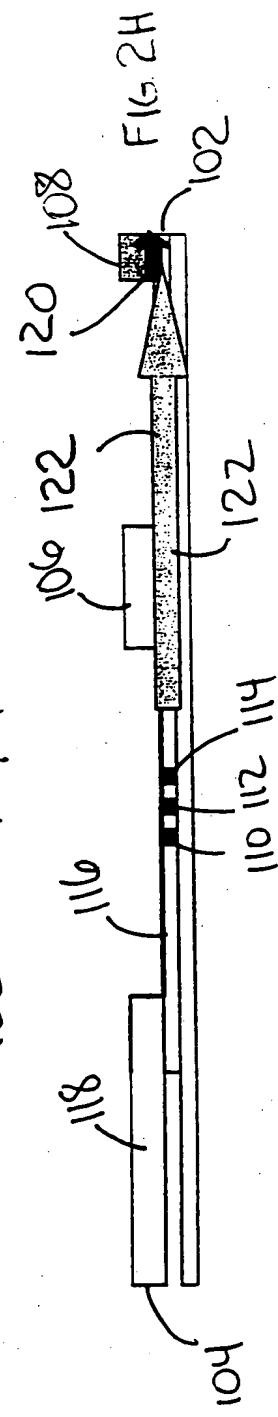


FIG. 2H

Add sample

Add buffer

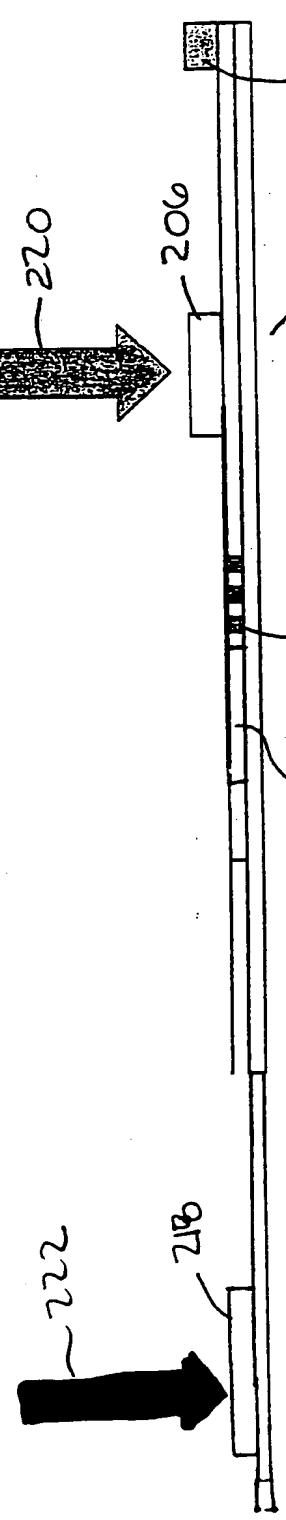
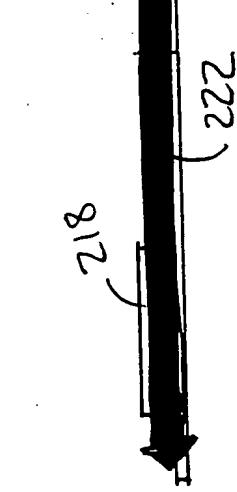
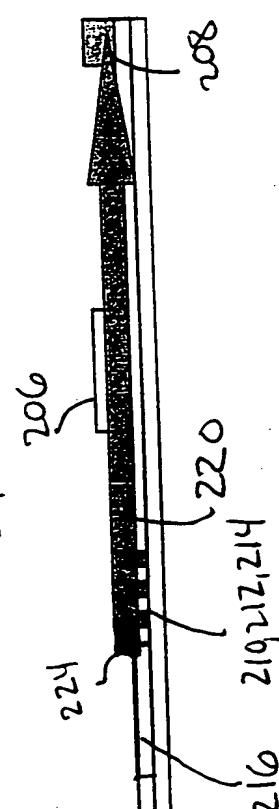
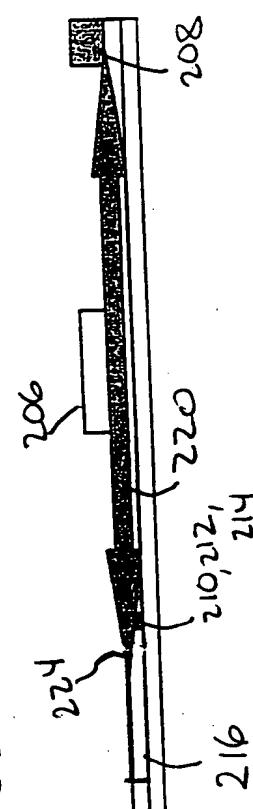
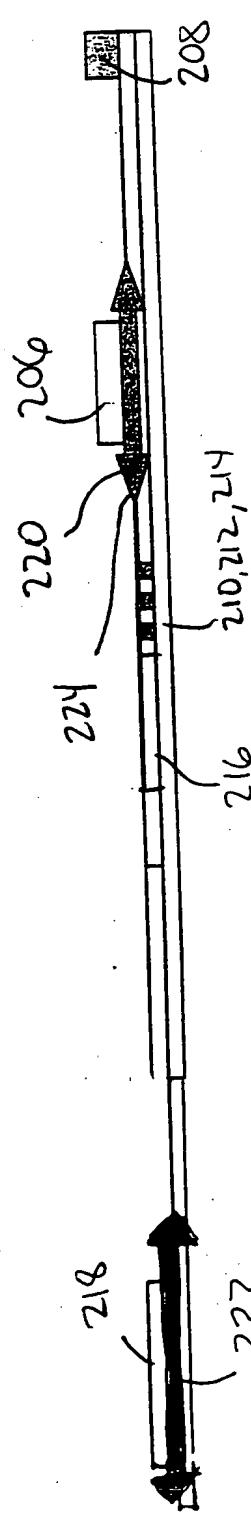


FIG. 3A

FIG. 3B

FIG. 3C

FIG. 3D



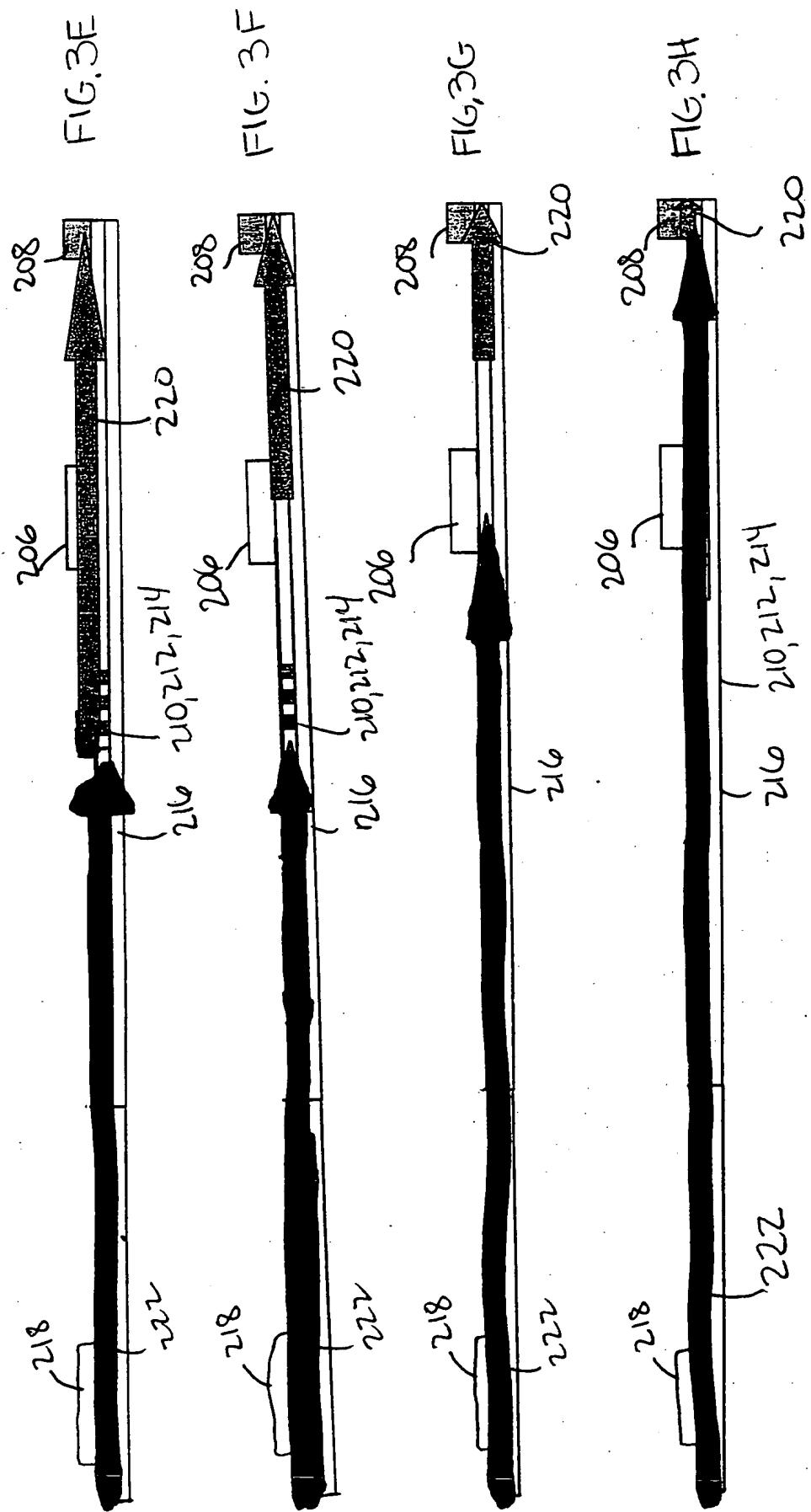


Fig. 4

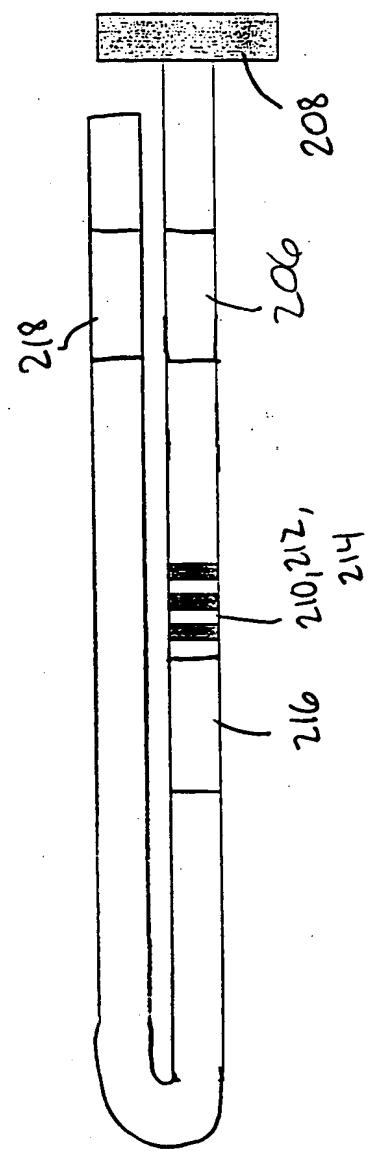


FIG. 5A

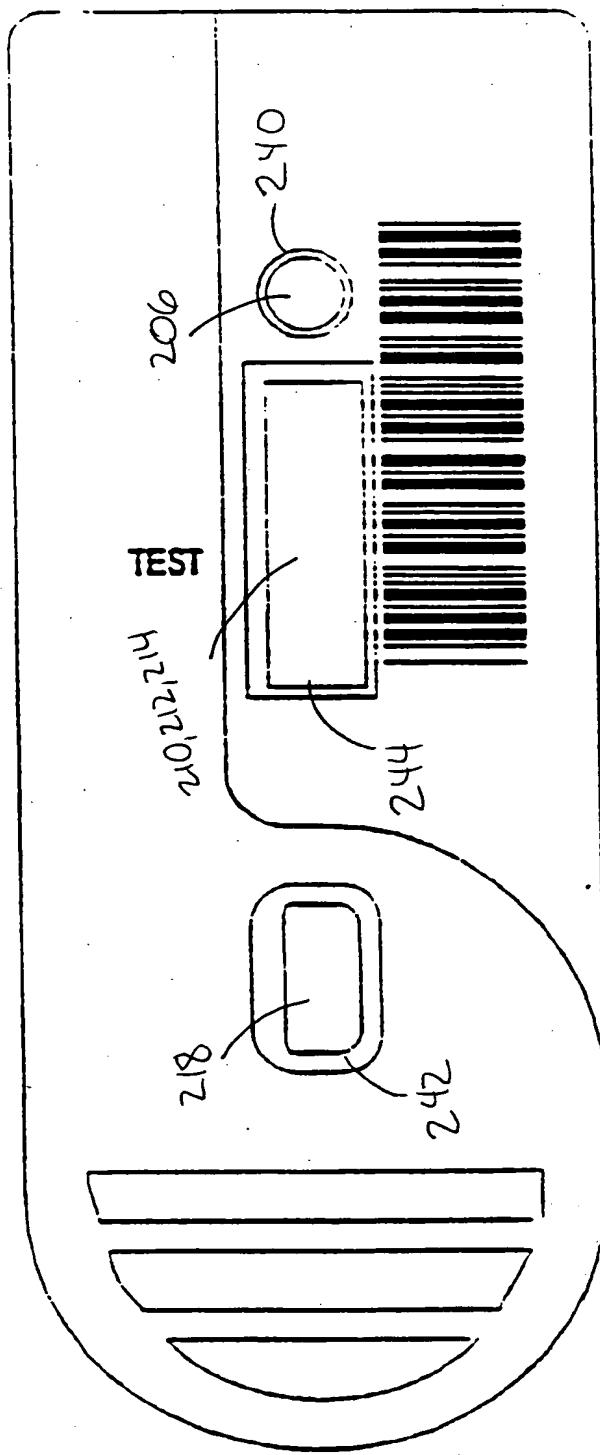


FIG. 5B

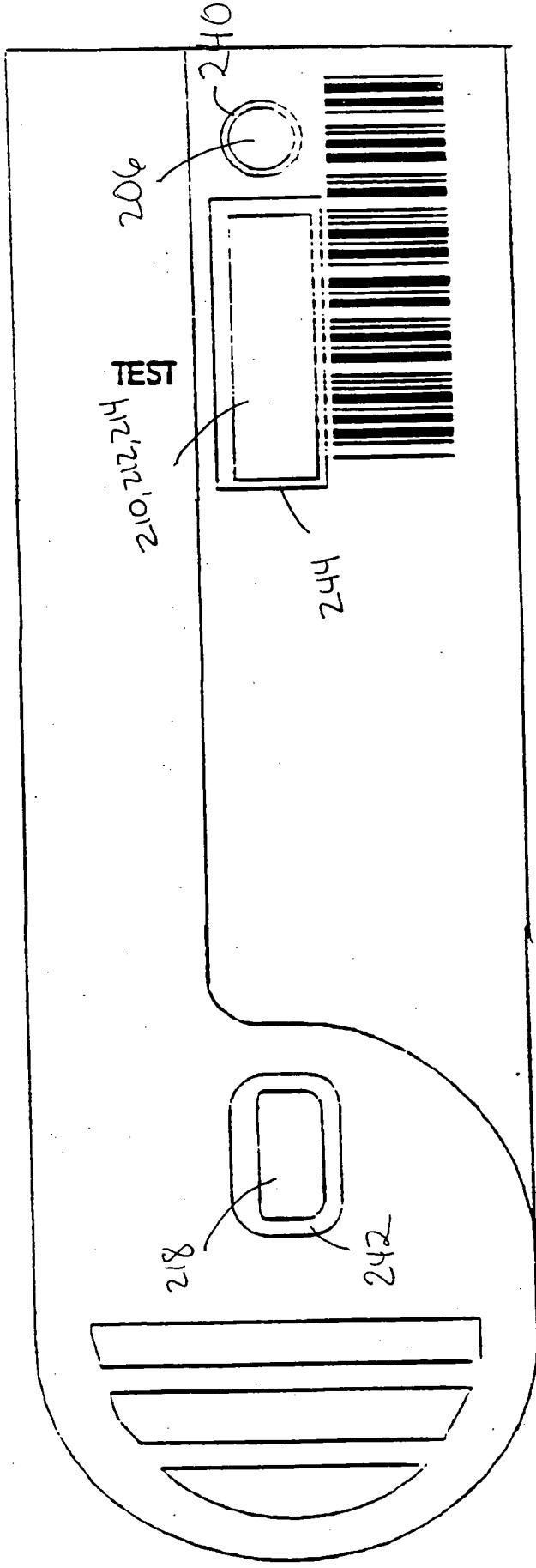


Fig. 5C

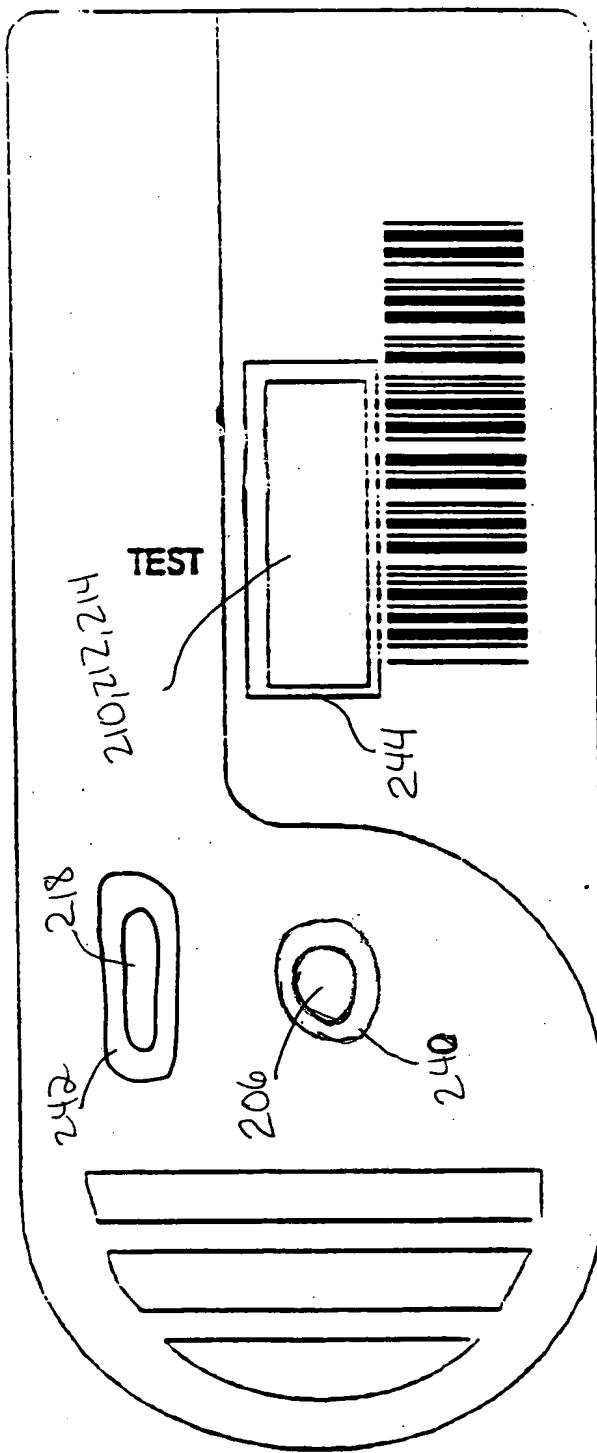


Fig. 6A

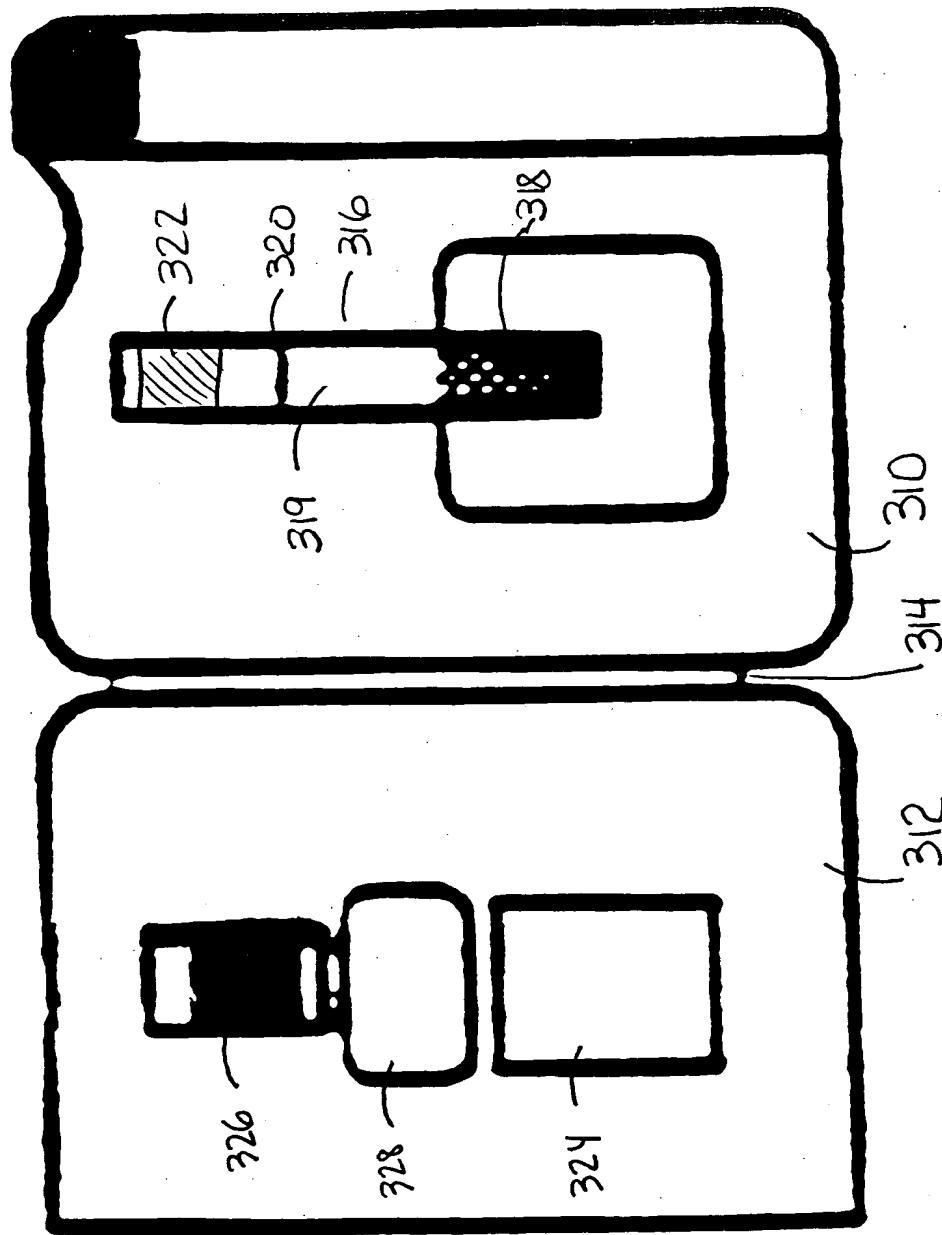
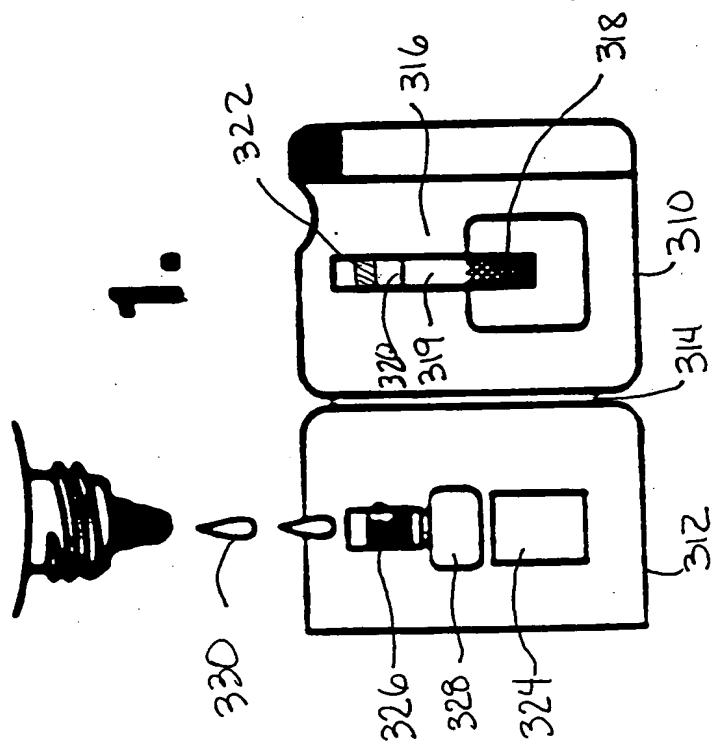
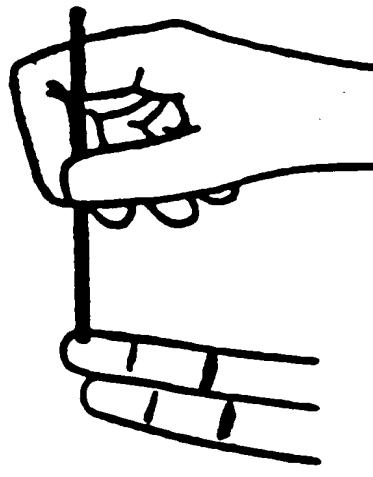


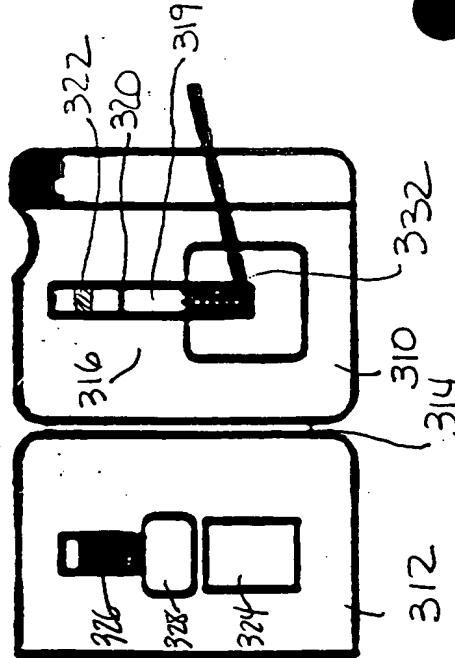
FIG. 6B



2.



3.



# ReLIA™ TSH (Goat Capture)

## 160 µg/ml BSA-DNP in Release Buffer

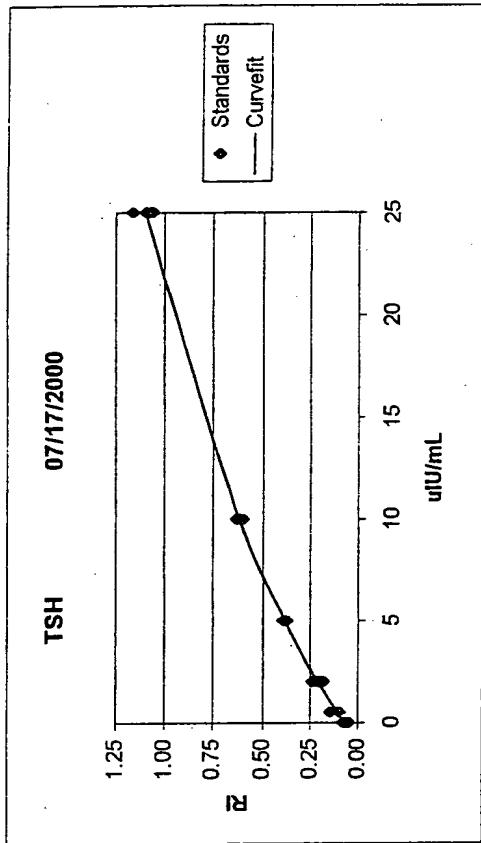
FIGURE 8

Sample	Sheet	Instrument	Hc (Dr)	Lc (Dr)	Specimen (Dr)	Hc/Lc	Specimen/HC	uIU/ml
4A	56R	104	0.3229	0.2308	0.2153	1.399	0.6667	9.21
4A	53R	120	0.3306	0.2371	0.2073	1.394	0.6270	8.48
4A	41R	110	0.3002	0.2394	0.2010	1.254	0.6695	9.26
4A	37R	163	0.3252	0.2569	0.2112	1.266	0.6496	8.89
4A	33R	115	0.2941	0.2414	0.1942	1.218	0.6605	9.08
4A	29R	107	0.3031	0.2080	0.1980	1.457	0.6532	8.95
4A	27R	146	0.3375	0.2200	0.1980	1.534	0.5867	7.74
4A	24R	111	0.3136	0.2235	0.2010	1.403	0.6410	8.72
4A	21R	104	0.2995	0.2119	0.2024	1.413	0.6755	9.37
4A	18R	120	0.3213	0.2291	0.1959	1.403	0.6097	8.16
4A	14R	110	0.2902	0.2105	0.1917	1.378	0.6607	9.10
4A	12R	163	0.3176	0.2333	0.2128	1.361	0.6699	9.27
4A	9R	115	0.3156	0.2243	0.2050	1.407	0.6494	8.88
4A	7R	107	0.3170	0.2213	0.2140	1.432	0.6751	9.37
4A	4R	146	0.3367	0.2329	0.2110	1.446	0.6265	8.46
4A	3R	111	0.3409	0.2426	0.2237	1.405	0.6562	9.01
Avg			0.3166	0.2289	0.2052	1.3856	0.6486	8.87
STD DEV			0.0158	0.0132	0.0089	0.0799	0.0250	0.46
%CV			5.0	5.7	4.3	5.8	3.9	5.2

**TSH (RI = antigen Dr/HC Dr)**  
7/17/00

**FIGURE 9**

Standard	RI	Standards	Fitted RI
0.0	0.046	0	0.060
0.0	0.049	0.5	0.104
0.0	0.058	2.0	0.210
0.0	0.078	5.0	0.384
0.5	0.094	10.0	0.618
0.5	0.0945	25.0	1.098
0.5	0.0955		
0.5	0.1471		
2.0	0.1801		
2.0	0.2365		
2.0	0.2146		
2.0	0.1970		
5.0	0.3889		
5.0	0.3788		
5.0	0.3926		
5.0	0.3730		
10.0	0.6198		
10.0	0.6262		
10.0	0.6301		
10.0	0.6026		
25.0	1.0938		
25.0	1.0580		
25.0	1.0755		
25.0	1.1618		



Standards:	0 uIU/ml	0.5 uIU/ml	1 uIU/ml	2 uIU/ml	5 uIU/ml	10 uIU/ml	25 uIU/ml
chi-squared	0.57						
K0							
K1							
K2							
K3							
Standards:	0 uIU/ml	0.5 uIU/ml	1 uIU/ml	2 uIU/ml	5 uIU/ml	10 uIU/ml	25 uIU/ml
Mean:	0.058	0.109	0.207	0.383	0.620	1.097	
SD:	0.014	0.026	0.024	0.009	0.012	0.045	
CV	24.62	23.67	11.67	2.35	1.96	4.14	
Standards:	0 uIU/ml	0.5 uIU/ml	1 uIU/ml	2 uIU/ml	5 uIU/ml	10 uIU/ml	25 uIU/ml
Mean:	0.046	0.570	1.967	4.980	10.035	25.027	
SD:	0.092	0.342	0.372	0.170	0.291	1.866	
CV	200.00	59.91	18.90	3.42	2.90	7.46	

## ReLIA™ PSA (Goat Capture)

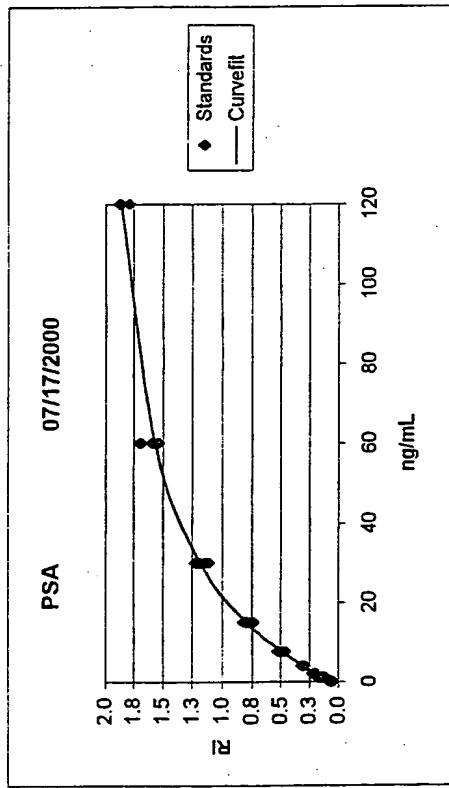
## 160 µg/ml BSA-DNP in Release Buffer

FIGURE 10

Sample	Sheet	Instrument	Hc (Dr)	Lc (Dr)	Specimen (Dr)	Hc/Lc	Specimen/HC	ng/ml
2A	HF 135-24	163	0.2438	0.2469	0.1206	0.987	0.4948	9.70
2A	HF 135-23	165	0.2243	0.2252	0.0969	0.996	0.4318	8.20
2A	HF 135-20	104	0.2883	0.2543	0.1352	1.134	0.4690	9.07
2A	HF 135-21	120	0.2188	0.2165	0.0996	1.011	0.4553	8.75
2A	HF 135-31	115	0.2448	0.2113	0.1123	1.159	0.4586	8.83
2A	HF 135-30	107	0.2301	0.2283	0.1177	1.008	0.5117	10.11
2A	HF 135-27	111	0.2149	0.1825	0.1094	1.177	0.5089	10.05
2A	HF 135-25	146	0.2329	0.2206	0.1078	1.056	0.4629	8.93
2A	HF 135-36	163	0.2907	0.2558	0.1342	1.136	0.4617	8.90
2A	HF 135-35	165	0.3104	0.2988	0.1237	1.039	0.3984	7.45
2A	HF 135-33	104	0.2467	0.2507	0.1133	0.984	0.4595	8.85
2A	HF 135-34	120	0.2424	0.2270	0.1288	1.068	0.5313	10.62
2A	HF 135-18	115	0.2535	0.2529	0.1150	1.002	0.4535	8.71
2A	HF 135-37	107	0.2784	0.2633	0.1300	1.057	0.4672	9.02
2A	HF 135-19	111	0.2702	0.2701	0.1158	1.000	0.4288	8.14
2A	HF 135-29	146	0.2624	0.2314	0.1185	1.134	0.4515	8.66
Avg			0.2533	0.2397	0.1174	1.0593	0.4653	9.00
STD DEV			0.0279	0.0275	0.0112	0.0673	0.0334	0.80
%CV			11.0	11.5	9.5	6.4	7.2	8.9

**PSA**  
0706-HF135

Figure 11



ng/mL	0.0	0.0713	0.0	0.076
0.0	0.0606	0.0	0.130	0.0
0.0	0.0641	0.0	0.187	0.0
0.0	0.0511	0.0	0.301	0.0
1.0	0.1178	1.0	0.481	1.0
1.0	0.1126	1.0	0.789	1.0
1.0	0.1754	1.0	1.182	1.0
1.0	0.1501	1.0	1.565	1.0
1.0	0.1202	1.0	1.853	1.0
1.0	0.1432	1.0	0.2127	1.0
2.0	0.1927	2.0	0.1832	2.0
2.0	0.1933	2.0	0.2926	2.0
2.0	0.2127	2.0	0.3007	2.0
4.0	0.3082	4.0	0.2891	4.0
4.0	0.2926	4.0	0.2891	4.0
7.5	0.5187	7.5	0.4582	7.5
7.5	0.5072	7.5	0.5072	7.5
15.0	0.8110	15.0	0.7819	15.0
15.0	0.7861	15.0	0.7861	15.0
15.0	0.7382	15.0	0.7382	15.0
30.0	1.2190	30.0	1.1140	30.0
30.0	1.1931	30.0	1.1507	30.0
60.0	1.5443	60.0	1.5563	60.0
60.0	1.5426	60.0	1.6845	60.0
120.0	1.7872	120.0	1.8674	120.0

ng/ml	0 ng/ml	1 ng/ml	2 ng/ml	4 ng/ml	7.5 ng/ml	15 ng/ml	30 ng/ml	60 ng/ml	120 ng/ml
Mean	0.062	0.139	0.190	0.298	0.463	0.779	1.169	1.565	1.827
SD	0.01	0.03	0.01	0.01	0.03	0.03	0.05	0.03	0.06
CV	13.59	21.16	2.99	2.87	6.61	3.88	3.96	1.90	3.10
	0.00	0.79	2.09	4.14	7.29	15.63	31.95	57.56	99.70
	0.00	0.70	1.93	3.86	8.29	14.79	26.72	62.64	125.63
	0.00	1.79	2.10	4.00	7.02	14.91	30.57	57.36	
	0.00	1.36	2.44	3.79	8.05	13.58	28.44	79.25	
	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.83
	1.24	1.24	1.24	1.24	1.24	1.24	1.24	1.24	1.24
Mean	0.00	1.12	2.04	3.95	7.53	14.73	29.42	60.10	112.66
SD	0.00	0.42	0.10	0.15	0.67	0.85	2.31	3.59	18.33
CV	37.74	4.80	3.92	8.88	5.79	7.86	16.27	5.98	

FIGURE 12

Comparison of ReLiA TSH Assay With Sample Added to Top and Bottom Ports Versus Sample Added to Bottom Port Only

Sample		Sample Added to Top				No Sample Added to Top			
		HCDR	Specimen DR	Specimen DR HCDR	TSH (uIU/ml)	HCDR	Specimen DR	Specimen DR HCDR	TSH (uIU/ml)
S-25 Spiked	Mean	0.2499	0.0243	0.0973	1.9088	0.204	0.0249	0.1262	2.4425
	SD	0.0154	0.017	0.0054	0.101	0.0359	0.007	0.0292	0.5276
	CV	6.2%	7.0%	5.5%	5.3%	17.6%	2.9%	23.1%	21.6%
S-42 Spiked	Mean	0.2566	0.0869	0.3399	6.2871	0.2219	0.0895	0.4055	7.4928
	SD	0.0199	0.0054	0.0275	0.4981	0.0249	0.0057	0.0281	0.5252
	CV	7.8%	6.3%	8.1%	7.9%	11.2%	6.4%	6.9%	7.0%
Pod A	Mean	0.2541	0.1369	0.5436	10.1692	0.2338	0.1394	0.6035	11.418
	SD	0.0312	0.0093	0.0497	1.0085	0.0362	0.0133	0.0675	1.4461
	CV	12.3%	6.8%	9.2%	9.9%	15.5%	9.6%	11.2%	12.7%
Pod B	Mean	0.2613	0.031	0.1186	2.308	0.2147	0.0289	0.1358	2.6254
	SD	0.0164	0.0021	0.0082	0.1526	0.0289	0.0025	0.0128	0.2336
	CV	6.3%	6.8%	6.9%	6.6%	13.4%	8.7%	9.4%	8.9%

FIGURE 13

Reproducibility of the ReLIA TSH Assay With Sample added to Top and Bottom

TSH LEVEL	ReLIA Result in $\mu$ IU/mL (N = 8 Replicates)		
Normal (Approx. 1 $\mu$ IU/mL)	Mean	1.0712	
	SD	0.089	
	CV	8.3%	
Borderline Elevated (Approx. 5 $\mu$ IU/mL)	Mean	6.2425	
	SD	0.551	
	CV	8.8%	
Elevated (Approx. 25 $\mu$ IU/mL)	Mean	23.631	
	SD	1.658	
	CV	7.0%	

FIGURE 14

